



DEPARTMENT OF HEALTH AND HUMAN SERVICES

c/1900b
Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

OK
6/29/98
June 29, 1998

Certified Mail-Return Receipt Requested

Henry Born, MD
Program Sponsor
Calhoun Treatment Center, Inc.
118 Choccolocco St.
Oxford, AL 36203

Warning Letter No. 98-NSV-18

Dear Dr. Born:

On April 29 - May 1, 1998, Food and Drug Administration (FDA) Investigator Patricia S. Smith inspected Calhoun Treatment Center, Inc., located at the above address.

Our review and evaluation of the investigator's report revealed the following significant violations of the Narcotics Treatment Program Standards, 21 CFR 291.505, Conditions for the Use of Narcotic Drugs:

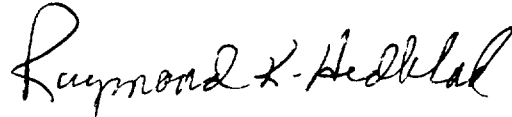
- o You failed to assure that a medical evaluation and physical examination were performed before several patients were entered or re-admitted to maintenance treatment. [21 CFR 291.505(d)(3)(i)]
- o You failed to provide and/or document counseling on preventing exposure to and transmission of HIV disease for four of the eighteen patients whose records were reviewed. [21 CFR 291.505(d)(4)(i)(C)]
- o You failed to sign annual reviews of treatment plans in seventeen of the eighteen patient file records that were reviewed. [21 CFR 291.505(d)(3)(v)(C)]
- o You failed to obtain FDA approval for each phase advancement including medication take-home requirements for patient no. 049. [21 CFR 291.505(d)(6)(v)]

The above noted violations and the observations listed on the enclosed copy of the FDA Form 483 are not intended to be all inclusive. It is your responsibility as sponsor to ensure that your program remains in compliance with all federal and state laws and regulations.

Failure to effectively and promptly correct the noted violations, or any further violations of the requirements set forth at 21 CFR 291, may result in enforcement action without further notice.

We acknowledge receipt of the May 29, 1998, response to the FDA Form 483, but we request your response within fifteen (15) days of receipt of this letter detailing any additional corrections you have taken or plan to take to prevent recurrence of these violations. Your response should be directed to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,

A handwritten signature in cursive script, reading "Raymond K. Hedblad".

Raymond K. Hedblad
Director, Nashville District

RKH:FJJ:mrd

Enclosure